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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,961	04/16/2004	David R. Miller	022175-000200US	8211
20350 7590 07/24/2007 TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			EXAMINER BOUCHELLE, LAURA A	
			ART UNIT 3763	PAPER NUMBER
			MAIL DATE 07/24/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/825,961

Applicant(s)

MILLER ET AL.

Examiner

Laura A. Bouchelle

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3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-51, 53 and 56-63 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 6-8, 11-13, 15, 22-25, 29-33, 35, 36, 40-42, 45-47, 49, 53, 59, 60, 63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

Continuation of Disposition of Claims: Claims withdrawn from consideration are 3-5,9,10,14,16-21,26-28,34,37-39,43,44,48,50,51,56-58 and 61.

DETAILED ACTION

Response to Amendment

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1, 2, 6-8, 11-13, 15, 22-25, 33, 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sharkey et al (US 7069087) in view of Goltzer (US 4973305). Sharkey discloses a method for introducing substances into an intervertebral disc including all the elements and steps set forth in the claims, except for anchoring the distal portion such that the distal portion remains anchored when the patient changes positions. Goltzer teaches a method for retaining an epidural catheter comprising the steps of inflating a balloon to anchor the distal end of the catheter in the desired location so that the catheter remains securely fixed in the desired location (abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to include the step of anchoring the distal end of the catheter in place as taught by Goltzer so that the patient can move without dislodging the catheter.
3. Claims 24, 53 differ from the teachings above in calling for the introduction of a placebo into the disc. It would have been obvious to one having ordinary skill in the art at the time of invention to use a placebo as the substance delivered since Sharkey and

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Goltzer teach that their methods/devices are capable of delivering substances and could also deliver a placebo, and delivering a placebo is well known in the art.

4. Claims 25, 31, 32, 35, 36, 40-42, 45-57, 49, 60, 62, 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sharkey in view of Goltzer as applied to claim 1 above, and further in view of Sluijter et al (US 5433739). Claims 25, 35 differ from the teachings above in calling for the steps of causing the patient to assume a position where pain is experienced and introducing an anesthetic or analgesic into the disc. Sluijter teaches a method for treating back pain including the steps of inserting a catheter in to the disc of a patient and introducing an anesthetic solution into the disc and observing the effect on the patient's pain (Col. 14, lines 12-13, 21-25). In this method, it is inherently disclosed that the patient has assumed a position where spinal pain is experienced because that would be a necessary step in determining the effect of the treatment on pain experienced. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the method disclosed above to include the steps of having the patient assume a position where pain is experienced and introducing an analgesic into the disc as taught by Sluijter so that the effect of the treatment on back pain can be determined.

5. Claims 29, 30, 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sharkey in view of Goltzer as applied to claim 25 above, and further in view of Diederich et al (US 2003/0216721). Claims 29 and 30 differ from the teachings above in calling for the step of performing a discography procedure. Diederich teaches performing a

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discography procedure to determine the discs to be treated and to monitor the progress of the treatment (Page 15, paragraph 0235, 0239). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the method above to include the step of performing a discography as taught by Diederich to determine the discs to be treated and to monitor the progress of the treatment.

Response to Arguments

6. Applicant's arguments filed 5/17/2007 have been fully considered but they are not persuasive.

7. Applicant argues that one skilled in the art would not look to the teachings of Goltzer to modify the method taught by Sharkey. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Goltzer teaches that it is well known in the art to use a balloon to affix a catheter in a desired location. Furthermore, as applicant points out, it is an inflatable member on the distal end of a catheter is a well known technique in the art to secure a catheter in the desired location.

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8. Applicant argues that Sluijter does not teach that the patient is in a position in which pain is experienced. Sluijter teaches that the analgesic is administered and the effect on pain is determined. Clearly the patient is in a position in which pain is experienced since the effect of the treatment on the pain could not be observed if the patient was already in a pain-free position.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura A. Bouchelle whose telephone number is 571-272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



CATHERINE S. WILLIAMS
PRIMARY EXAMINER

Laura A Bouchelle
Examiner
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